UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,429	04/12/2004	Peter Miller	INA-10902/08	4021

25006 7590 02/07/2008

GIFFORD, KRASS, SPRINKLE,ANDERSON & CITKOWSKI, P.C
PO BOX 7021
TROY, MI 48007-7021

EXAMINER	
TATE, CHRISTOPHER ROBIN	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,429	MILLER ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10-12,14 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10-12,14 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 06 December 2007 is acknowledged and has been entered. Claims 1, 10-12, 14, and 22-24 have been examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 10-12, 14, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCabe (US 6,172,114) in view of Greenhaff et al. (US 5,968,900), Cheng (US 6,200,569) and Portman (US 6,051,236) for the reasons set forth in the previous Office action.

Applicants' arguments concerning the above rejection have been carefully considered but are not deemed to be persuasive of error in the rejection.

Applicants argue that - as acknowledged by the previous examiner, the McCabe reference does not teach the use of any water-soluble extract of cinnamon in combination with creatine and carbohydrates, that the Greenleaf reference teaches creatine and carbohydrates, and that increasing the amount of creatine within a muscle favorably affects muscular performance, but the examiner does not tie this role of glycogen in any way to the presence of creatine in muscles (however, please note the examiner further discussed that McCabe discloses glycogen is convertible from and to glucose and athletes endeavor to increase muscle glycogen content before competing in order to enhance muscle performance); that the Cheng reference teaches

water soluble cinnamon extracts as insulin potentiating agents effective to lower glucose (however, please note the examiner further discussed that Cheng discloses its preparation - which is the same as claimed, that such an insulin potentiating agent increases insulin activity as measured by increases glucose uptake by cells; that improved insulin activity leads to decreased circulating insulin which leads to lower blood glucose; that glucose is used in cellular metabolism to product energy or is converted to glycogen for storage in the muscles, and that the dry powder thereof can be a single component of cinnamon); that the Portman teaches a nutritional composition based upon carbohydrates (however, please note that the examiner further discussed that Portman teaches that the nutritional composition is for optimizing muscle performance during exercise and for enhancing muscle repair following exercise, that the carbohydrates therein, such as dextrose, maltose, and maltodextrin, are used to replenish muscle glycogen, and that the carbohydrate-containing composition is sufficient to stimulate glucose transport, glycogen synthesis and muscle repair). Applicants have argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references.

Applicants further arguments on pages 6 and 12 of their 06 December 2007 with regard to the blanket statement concerning the synergistic interaction of creatine and water-soluble cinnamon extract are not deemed persuasive - i.e., the Examiner could not find sufficient

evidence of synergism (e.g., above that which would be normally expected) with respect to the combination of creatine and water-soluble cinnamon extract. Please also note that synergism is an unexpected result which is well recognized to be an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit sufficient evidence of such unexpected results (e.g., synergism) is considered obvious and, thus, unpatentable - i.e., the instant claims, in the range of proportions where no unexpected results (i.e., synergism) are observed (e.g., demonstrated) would have been obvious to one of ordinary skill having the above cited references before him/her (as well as the combined cited references within the other USC 103 rejections set forth below).

Claims 1, 10-12, 14, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCabe (US 6,172,114) in view of Portman (US 6,051,236) and, if necessary, Miller et al.* (US 6,903,136 - please note that the effective filing date of this document is 22 April 2002, based upon the provisional application filing date).

McCabe beneficially teaches a body-building supplement composition (including in the form of a solution) comprising creatine monohydrate in combination with a carbohydrate (ribose), within various amount levels (apparently within certain claim amount levels - see, e.g., claim 23) which is useful for increasing muscle mass, strength, and energy (see entire document including abstract; col 1, line 11 - col 2 line 42; and claims). McCabe does not expressly teach the inclusion of a water-soluble cinnamon extract or the particular carbohydrates instantly claimed (such as recited in instant claim 10).

Portman beneficially teaches a nutritional supplement composition (including in the form of a solution and/or beverage) for optimizing muscle performance during exercise which comprises (or may comprise) high levels of carbohydrates such as dextrose, maltose, and maltodextrin therein as a high glycemic energy source and to replenish muscle glycogen supplies. Portsman also beneficially teaches the inclusion of a water-soluble extract such as a water-soluble cinnamon extract as a flavoring agent so as to advantageously impart a particular taste and sometimes an aroma to the nutritional composition, whereby the flavoring agent is at a level of 0.1 to 2.0 %w/w within the nutritional composition (please note that this level of water-soluble cinnamon extract therein would intrinsically function, as well as comprise a fraction which is soluble in 0.1 N acetic acid, as instantly claimed) - see entire document including col 11, lines 11-38 and col 13, lines 44-53.

If necessary, Miller et al. teach a nutritional dietary supplement (including in the form of a solution and/or beverage) which is useful for enhancing athletic performance and building muscle mass which comprises (or may comprise) creatine monohydrate (which Miller et al. disclose is commonly recommended in order to enhance muscle size, strength, and performance including following exercise), an extract of cinnamon (which Miller et al. disclose acts as a glucose-modifying or blood insulin-modifying agent) such as methyl hydroxy chalcone polymer (which as readily admitted by Applicants reads upon a water-soluble extract of cinnamon, as instantly claimed: see, e.g., last two paragraphs on page 7 of the instant specification), and one or more carbohydrates (which Miller et al. disclose act to provide a high glycemic index in order to cause a rapid increase in the blood glucose level) such as dextrose or maltose (each apparently within similar amount ranges as those instantly claimed).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a nutritional supplement composition (including in the form of a solution and/or beverage) comprising creatine monohydrate (such as taught by McCabe and, if necessary, by Miller et al.), a water extract of cinnamon (such as the flavoring agent taught by Portsman and, if necessary, the water-soluble methyl hydroxy chalcone polymer extracted from cinnamon taught by Miller et al), and one or more carbohydrates (including those taught by Portsman and, if necessary, by Miller et al), based upon the beneficial teachings provided by the cited references with respect to incorporating such ingredients within a nutritional and/or dietary supplement composition for such purpose. With respect other ingredients that may be taught by the cited references, please note that the omission of an element and its function is obvious if the function of the element is not desired (see, e.g., *Ex parte Wu*, 10 USPQ 2031, 1989 - MPEP 2144.04). The adjustment of particular conventional working conditions (e.g., determining appropriate amount levels thereof) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please also note that the post-use limitations recited in claim 14 have not been accorded patentable weight since the instant claims are drawn to a product, *per se*, not to its method of use.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

*The applied reference above (Miller et al.) appears to have a common inventor with the instant application (i.e., Paul Miller). Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art, only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) - as it applies to Miller et al. (which, please note, is an optional reference - i.e., "if necessary") - might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application

which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1, 10-12, 14, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krotzer (US 2001/0008641) in view of Portman (US 6,051,236).

Krotzer beneficially teaches a nutritional supplement composition for bodybuilding (including in the form of a solution and/or beverage) which comprises, or may comprise (including as the sole active ingredients therein) creatine monohydrate (designated as a component A), cinnamon (designated as a component D), and glucose or maltose (designated as a component C) therein (see entire document including paragraphs [0011] - [0031], [0060], and Tables A, B, & D). Krotzer does not expressly teach the inclusion of a water-soluble cinnamon extract therein. However, it should be noted that the incorporation of cinnamon within such a solution/beverage would intrinsically read upon a water-soluble cinnamon extract therein since cinnamon is well known in the herbal art to be ground bark from the *Cinnamonum* plant and that the ground bark is naturally water-soluble (thus, ground cinnamon within such a solution/beverage would result in the cinnamon therein reading upon a water-soluble cinnamon extract, as well as one that would intrinsically comprise a fraction which is soluble in 0.1 N acetic acid, as instantly claimed).

Portman beneficially teaches a nutritional supplement composition (including in the form of a solution and/or beverage) for optimizing muscle performance during exercise which comprises (or may comprise) a water-soluble extract such as a water-soluble cinnamon extract as a flavoring agent so as to advantageously impart a particular taste and sometimes an aroma to the nutritional composition, whereby the flavoring agent is at a level of 0.1 to 2.0 %w/w within the nutritional composition (please note that this level of water-soluble cinnamon extract therein would intrinsically function as instantly claimed, and would also intrinsically comprise a fraction which is soluble in 0.1 N acetic acid as instantly claimed).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a nutritional supplement composition (including in the form of a solution and/or beverage) comprising creatine monohydrate (as component A - as taught by Krotzer), a carbohydrate such as glucose and/or maltose (as component C - as taught by Krotzer), and a water soluble extract of cinnamon (such as the cinnamon taught by Krotzer - which, as discussed above, would intrinsically read upon a water-soluble extract when added to an aqueous solution/beverage; or the water-soluble extract taught by Portsman - as a flavoring agent, which would intrinsically function as claimed), based upon the beneficial teachings provided by the cited references with respect to incorporating such ingredients within a nutritional and/or dietary supplement composition for such purpose. With respect other ingredients that may be taught by the cited references (e.g., the other ingredients taught by Portsman et al), please note that the omission of an element and its function is obvious if the function of the element is not desired (see, e.g., *Ex parte Wu*, 10 USPQ 2031, 1989 - MPEP 2144.04). The adjustment of particular conventional working conditions (e.g., determining

appropriate amount levels thereof) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please also note that the post-use limitations recited in claim 14 have not been accorded patentable weight since the instant claims are drawn to a product, *per se*, not to its method of use.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher R. Tate
Primary Examiner
Art Unit 1655